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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,556	01/31/2001	Mitchell Anthony DeLong	79999	4976

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EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/774,556	DELONG ET AL.
	Examiner Lauren Q Wells	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,16,21-25,35,36,40,47 and 50 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claims 1-51 are pending. Claims 11-12, 16, 21-25, 35-36, 40, 47, and 50 are withdrawn from consideration, as they are directed toward non-elected subject matter.

The Petition to Withdrawn Holding of Abandonment (Paper No. 5) was granted on 12/9/02 (Paper No. 6). The Application has thus been restored to a pending status.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-49, 51, drawn to a composition comprising an active ingredient consisting of oximyl and hydroxylamino prostaglandins having the functionality as recited in claim 1 and a carrier, classified in class 514, subclass 573.
- II. Claim 50, drawn to a mascara composition comprising an active ingredient consisting of oximyl and hydroxylamino prostaglandins having the functionality as recited in claim 50, a water insoluble material, a water-soluble film forming polymer, a wax, a surfactant, a pigment, and a solvent, classified in class 424, subclass 70.7.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group I is a composition administered topically or systemically to a patient to enhance hair growth and group II is a mascara composition comprising cosmetic constituents, wherein a mascara composition is a hair coloring composition.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Claims 1-51 are generic to a plurality of disclosed patentably distinct species comprising compositions and methods for treating hair loss using oximyl and hydroxylamino prostaglandins. In particular, the compositions comprise an active ingredient, a carrier, and an activity enhancer. Possible active ingredients include the 96 prostaglandins in Table 1 and Table 2 on pages 14-31 of the specification. Possible carriers include water, aloe vera gel, allantoin, glycerin, vitamin A oil, vitamin E oil, mineral oil, propylene glycol, propylene glycol-2-myristyl propionate, dimethyl isosorbide, stearyl alcohol, glyceryl monoricinoleate, glyceryl monostearate, propane-1,2-diol, butane-1,3-diol, mink oil, cetyl alcohols, isopropyl isostearate, stearic acid, isobutyl palmitate, isocetyl stearate, oleyl alcohol, isopropyl laurate, hexyl laurate, decyl oleate, octadecan-2-ol, isocetyl alcohol, cetyl palmitate, di-n-butyl sebacate, isopropyl myristate, isopropyl palmitate, isopropyl stearate, butyl stearate, polyethylene glycol, triethylene glycol, lanolin, sesame oil, coconut oil, arachis oil, castor oil, acetylated lanolin alcohols, petrolatum, mineral oil, butyl myristate, isostearic acid, palmitic acid, isopropyl linoleate, lauryl lactate, myristyl lactate, decyl oleate, myristyl myristate, polydimethylsiloxane, propane, butane, isobutene, dimethyl ether, carbon dioxide, nitrous oxide, ethyl alcohol, methylene chloride, isopropanol, castor oil, ethylene glycol, monoethyl ether, diethylene glycol monobutyl ether,

diethylene glycol monoethyl ether, dimethyl sulfoxide, dimethyl fomamide, tetrahydrofuran, glycerin, sorbitol, sodium-2-pyrrolidone-6-carboxylate, soluble collagen, dibutyl phthalate, gelatin, chalk, talc, fullers earth, kaolin, starch, gums, colloidal silicone dioxide, sodium polyacrylate, tetra alkyl ammonium smectites, trialkyl aryl ammonium smectites, magnesium aluminum silicate, fumed silica, carboxyvinyl polymer, sodium carboxymethyl cellulose, and ethylene glycol monostearate. Possible activity enhances include minoxidil, cromakalin, diazoxide, finastearide, cyproterone acetate, azelaic acid, flutamide, selenium sulfide, ketoconazole, triclocarbon, triclosan, zinc pyrithione, itraconazole, Asiatic acid, hinokitiol, miprocin, clinacycin hydrochloride, benzoyl peroxide, benzyl peroxide, minocycline and others found on pages 49-52 of the specification. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Len Louis on 2/20/02 a provisional election was made with traverse to prosecute the composition wherein 11-oximyl-15-methyl-17-(2-fluorophenyl)-17-trinor-PGD2 methyl ester is the active ingredient, wherein water is the carrier, and wherein minoxidil is the activity enhancer. During a telephone conversation with Frank Taffy on 1/7/03 a provisional election was made with traverse to prosecute Group I. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-12, 16,

21-25, 35-36, 40, 47, and 50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 20, 26-27, 44 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase “a heterogeneous group” and a “substituted heterogeneous group” in claims 1 (lines 12 and 14), 3 (see “R7”, “R8” and “R9” definitions), 26 (lines 12 and 14), 27 (see “R7”, “R8” and “R9” definitions), 51 (lines 12 and 14) is vague and indefinite, as its meaning is unclear. What chemical constituents are encompassed by such a phrase? The specification does not further define this phrase and one of skill in the art would not be apprised of its meaning.

(ii) Claims 20 and 44 are rejected for the use of improper Markush groups. See MPEP 2173.05(h) for examples of proper conventional or alternative Markush-type language (e.g., “. . . selected from the group consisting of . . . and . . .”). Is the carrier selected from “w” as a single unit or can the carrier be any one of the components recited after “w”)?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10, 13-15, 17, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by DeLong (WO 99/50241).

DeLong et al. teach C11 oxymyl and hydroxylamino prostaglandins useful as medicaments. Exemplified is a composition comprising 11-oxymyl-13,14-dihydro-17-(2-fluorophenyl) 17 trinor PGD, water, dextran 70, hydroxypropyl methylcellulose, sodium chloride, potassium chloride, disodium EDTA, benzalkonium chloride, and HCL and/or NaOH. Thus, DeLong and the instant invention both teach compositions comprising a carrier (water) and oximyl and hydroxylamino prostaglandins having the functionality of the structure recited in claim 1, wherein C is bonded with a cyclopentyl ring, R2 and R2 form a covalent bond, and R4 is H, and having the structure recited in claim 3, wherein R2 and R3 form a covalent bond, R4 is H, a is a single bond, c is a sing bond, W is (CH₂)₂, R1 is CO₂H, R5 and R6 are H, X is OH, Y is a direct bond, p is 2, q is 0, and Z is a substituted aromatic group. See pages 13 and 37-38.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 26-34, 37-39, 41-44, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLong as applied to claims 1-10, 13-15, 17, and 20 above.

DeLong is applied as discussed above. The reference further exemplifies 11-oximyl-15-ethyl-18-phenyl-18-dinor-PGD2 (Applicant's elected species), which meets the formula of the

instant claims when W is (CH₂)₂, R₁ is CO₂H, X is OH, Y is a bond, Z is an aromatic group, R₅ is C₂H₅ and H, R₆ is OH and H, p is 3, q is 0, a is a double bond, c is a single bond, and b is a double bond. The compositions are disclosed as being administered systemically through transdermal, oral, parenteral, topical, and/or intranasal routes. Lotions, creams, gels, tablets, capsules and others are disclosed forms of the composition. The composition is disclosed as being administered daily for weeks or a month. The composition is disclosed for use in dermatological disorders. The reference lacks an exemplification of administering the composition to a mammal. See pages 34-36.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the composition of DeLong et al. as being administered to a mammal because DeLong et al. teach their composition as being administered to a mammal and because of the expectation of treating ocular disorders, hypertension, fertility control, nasal congestion, neurogenic bladder disorder, gastrointestinal disorders, dermatological disorders, and osteoporosis in mammals.

Claims 19, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLong et al. as applied to claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 40-44, 48-49 above, and further in view of Nathanson (5,500,230).

DeLong et al. is applied as discussed above. The composition lacks a hair growth stimulant.

Nathanson teaches a method for the treatment of glaucoma with nitrogen containing guanylate cyclease activators. Exemplified is a method of treating glaucoma in an individual

Art Unit: 1617

comprising systemically administering a therapeutically effective amount of minoxidil. See Col. 18, lines 33-line 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the minoxidil of Nathanson to the composition of DeLong et al. because both Nathanson and DeLong et al. are directed toward treating glaucoma and it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980).

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeLong et al. as applied to claims 1-10, 13-15, 17-18, 20, 26-34, 37-39, 41-44, 48-49 above, and further in view of Johnstone (6,262,105).

DeLong et al. is applied as discussed above. The reference lacks a method of applying their composition to growing hair.

Johnstone teaches a method of enhancing hair growth comprising topically applying a composition comprising prostaglandins to the scalp and hair. It is further disclosed that prostaglandins useful in glaucoma treatment are useful in enhancing hair growth. See Col. 1, line 25-Col. 5, line 34; Col. 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of DeLong et al. as being applied to growing hair, as disclosed by Johnstone, because a) DeLong et al. teach their compositions, which comprise prostaglandins, for use in treating dermatological disorders; b) Johnstone teaches that prostaglandins, such as those that treat glaucoma, are also useful for enhancing the growth the

hair, and the prostaglandins of DeLong are disclosed as useful in treating glaucoma; thus, one of skill in the art would be motivated to apply the composition of DeLong et al. to growing hair because of the expectation of enhancing hair growth via vasodilation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
January 7, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

1/20/03